

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND
COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

v.

MDL No: 1:13-md-2419-RWZ

This Document Relates to:

Brady, et al. v. Unifirst Corporation, et al.
No: 1:14-cv-10284-RWZ

**DEFENDANTS, GURURAU SUDARSHAN, M.D.
CINCINNATI PAIN MANAGEMENT CONSULTANTS, INC. AND
CINCINNATI PAIN MANAGEMENT CONSULTANTS LTD.'S
MEMORANDUM OF LAW IN SUPPORT OF
THEIR MOTION TO DISMISS**

I. INTRODUCTION¹

This action arises out of a tainted steroid – preservative free methylprednisolone acetate (“MPA”) – manufactured and sold by New England Compounding Pharmacy Inc. (“NECP”). Plaintiffs allege that NECC’s negligent manufacturing and sterilization practices contaminated certain batches of MPA with a fungus that sickened the patients who ultimately received the steroid from their healthcare providers. According to Plaintiffs, the tainted vials were included in certain lots which NECC recalled in September, 2012: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.²

In addition to persons and entities affiliated with NECC, Plaintiffs have sued three Defendants – Dr. Gururau Sudarshan, Cincinnati Pain Management Consultants, Inc., and

¹ The facts set forth herein are derived from the short form complaint and the pleadings that it incorporates. Consistent with Fed. R. Civ. P12(B)(6), these facts are presumed true for purposes of this motion only.

² The Lot Number denotes the date of the lot’s manufacture or compounding.

Cincinnati Pain Management Consultants, Ltd.³ (hereinafter “CPM”). But as more fully set forth below, Plaintiffs do not state a viable claim and their complaint must be dismissed. Dr. Sudarshan and CPM did not manufacture or sell the MPA nor have any role or involvement in its contamination.. Instead, they merely purchased the MPA from NECC and used it in the normal course of their practice. Nothing more.

II. STATEMENT OF THE CASE AND RELEVANT FACTS

With respect to his care and treatment by these Defendants, Brady’s allegations are sparse. He asserts that Dr. Sudarshan administered the contaminated NECC drug to him at CPM, on approximately August 29, 2012. (Short Form Cmplt., ¶6). Following the injection, Brady claims that he developed pain and other symptoms as a result of the contamination. (Id., ¶ 11). He further alleges that eventually he was hospitalized and treated for “possible fungal meningitis” as a result of the contaminated MPA. (Id.).⁴

The claims against the NECC-affiliated defendants center on negligent manufacturing and sterility practices. But in the wake of the NECC bankruptcy, Plaintiffs are hunting for more pockets. On the slimmest of legal theories, they have cast a wide net and asserted claims against any healthcare provider that purchased the steroid from NECC and administered it. Plaintiffs contend that these doctors and clinics had a duty of “due diligence” before purchasing the MPA and that state regulations require individual prescriptions in the purchase of such compounding

³ Cincinnati Pain Management Consultants, Inc. does not exist. Its link to this case is unclear as it was dissolved in the mid-1990’s.

⁴ In addition to Dr. Sudarshan and CPM., Plaintiffs have also named Cincinnati Pain Management Consultants, Ltd. – which they claim is a successor in interest to the inactive or dissolved CPM. (Id., ¶6). Plaintiffs have also included as defendants various NECC-affiliated individuals and entities along with Unifirst Corporation, the company allegedly responsible for sanitation at the NECC facility. (See Master Cmplt, ¶¶ 136-150). The NECC-affiliated persons and entities include Ameridose LLC., GDC Properties Management, LLC, Medical Sales Management, Inc., Medical Sales Management SW, Inc., Barry Cadden, Gregory Conigliano. Lisa Cadden, Douglas Conigliaro, and Glenn Chin. An additional defendant includes ARL Bio Pharma Inc. It is alleged that Ameridose is a distribution center owned and controlled by NECC with it also alleged that NECC and Ameridose used MSM and MSMSW for marketing and sales functions. ARL, in turn, is alleged to have been retained by NECC to provide sterility testing, services and information to NECC. GDC was the owner or lessor of the premises leased by NECC where NECC operated. The individuals named (Conigliaros and Caddens) are alleged to be the owners, pharmacists and/or managers of NECC.

medications. Plaintiffs even go so far as to contend (dubiously) that the healthcare providers that somehow had an agency relationship with NECC, with Plaintiffs even invoking (inapplicable) product liability law in their effort to deepen the pool of potential contributors.

Plaintiffs initially filed this action in the Southern District of Ohio before it was transferred to the MDL docket. Following transfer, Plaintiffs adopted the Short Form Complaint. That pleading incorporates by reference both the original complaint and the master complaint. (Short Form Cmplt., ¶¶1, 15). Through these interrelated pleadings, the Plaintiffs appear to assert the following causes of action against Dr. Sudarshan and CPM: (1) Negligence and Gross Negligence (Count III); (2) Violations of Illinois Consumer Protection Laws (Count IV);⁵ (3) Battery (Count VII); (4) Failure To Warn (Count VIII); (5) Agency (Count X); (6) Civil Conspiracy (Count XI); (7) Loss Of Consortium (Count XIII); and (8) Punitive Damages (Count XIV). For the reasons that follow, these claims must be dismissed.

III. STANDARD

To survive a motion to dismiss, plaintiff must allege facts that “raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). “The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)(quoting *Twombly*, 550 U.S. at 556). The Court need not accept the plaintiff's legal conclusions as true or other “labels and conclusions” as “formulaic recitation of a cause of action’s elements will not do.” *Twombly*, 550 U.S. at 555. Similarly, the Court should not credit bald assertions or legal conclusions “couched as facts.” *Air Sunshine, Inc. v. Carl*, 663 F. 3d 27, 33 (1st Cir. 2011). Dismissal is appropriate if plaintiff's well-pleaded facts do not “possess

⁵ Illinois connection to this case is not clear. As alleged, Dr. Sudarshan and his practice are located in Cincinnati, Ohio.

enough heft to show that plaintiff is entitled to relief.” *Ruiz Rivera v. Pfizer Pharms., LLC*, 521 F.3d 76, 84 (1st Cir. 2008) (quotations and original alterations omitted).

IV. LAW AND ARGUMENT

A. Plaintiffs’ Complaint Fails to Sufficiently Allege Claims for Negligence and Gross Negligence.

1. Ohio law does not impose any of the “duties” alleged by Plaintiffs in the Complaint.

In Count III of the referenced Master Complaint, plaintiffs set forth what appears to be a laundry list of “duties” Dr. Sudarshan and CPM allegedly owed as a result of the physician-patient relationship. Under the guise of these “duties”, it is alleged that Dr. Sudarshan and CPM were required to investigate and supervise NECC’s compounding procedures and production facilities and engage in a “due diligence” of sorts prior to lawfully purchasing preservative-free MPA from NECC. However, no such duties exist under Ohio law. Accordingly, Count III fails to state a claim upon which relief can be granted.

A plaintiff must allege sufficient facts to meet each element of a negligence claim: “the existence of a duty, a breach of the duty, and an injury proximately resulting therefrom.” *Powell v. Hawkins*, 175 Ohio App. 3d 138, 143 , 885 N.E. 2d 958, 961 (2007); *Scatamacchio v. Western Rserve Healthcare*, 161 Ohio App. 3d 230, 829 N.E. 2d 1247, 1251 (2005); *Middleton v. Rogers Ltd., Inc.*, 804 F. Supp. 2d 632, 639 (S.D. Ohio 2011), citing *Nageotte v. Cafaro Co.*, 160 Ohio App.3d 702, 828 N.E.2d 683, 688 (6th Dist. 2005). Of note, “[t]he existence of a duty is fundamental to establishing actionable negligence, without which there is no legal liability.” *Uhl v. Thomas*, 12th Dist. No. CA 2008-06-131, 2009-Ohio-196, ¶ 10,. The existence of a duty in a negligence action is a question of law for the court to determine. *Mussivand v. David*, 45 Ohio

St.3d 314, 318, 544 N.E.2d 265, 270 (1989)(citing *Railroad Co. v. Harvey*, (77 Ohio St. 235, 240(1907)).⁶

Ohio law does not impose a duty on physicians and/or medical clinics to regulate the pharmacies from which they lawfully purchase medications, nor does Ohio law impose a duty on physicians to visit and/or evaluate a licensed pharmacy's compounding facility prior to purchasing medications as alleged. There is no authority supporting such a "due diligence duty" with there no reported case ever so holding or finding such a duty. Any duty resided with the Massachusetts Board of Pharmacy, not Dr. Sudarshan and CPM, as to any regulation of NECC and its compliance with applicable laws. Dr. Sudarshan and CPM were well within their legal right to purchase medication from a fully licensed pharmacy without independently investigating whether the pharmacy's sterility practices complied with applicable law. Ohio law does not require physicians and/or clinics to purchase medications from an FDA regulated drug manufacturer as Plaintiffs suggest. There was no due diligence duty as a matter of law.

Dr. Sudarshan and CPM were not required to follow the American Society of Health-System Pharmacy (ASHP) Guidelines on Outsourcing Sterile Compounding Services, nor do such guidelines establish any duty under Ohio law. ASHP is a professional organization for Health-System Pharmacies. It is not a governing body that has any authority over the actions of Ohio physicians and/or medical clinics. Such guidelines are professional guidelines that have no bearing on duties imposed by Ohio law.

Ohio law does not impose a duty on physicians to regulate pharmacies and/or engage in any type of due diligence prior to lawfully purchasing medications from a licensed pharmacy

⁶ There is no formula for ascertaining whether a duty exists. Duty is the court's "expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection." *Id.* (citation omitted). Any number of considerations may justify the imposition of duty in particular circumstances, including the guidance of history, our continually refined concepts of morals and justice, the convenience of the rule, and social judgment as to where the loss should fall. *Id.*

such as NECC. Ohio law has never recognized any such duties with respect to physicians and/or clinics. Moreover, it is for the Ohio General Assembly, not the courts, to determine whether any such duties should be imposed on physicians and/or clinics. See generally, *Crum v. Lambe*, 1987 WL 15496 (Ohio App. 4 Dist. 1987) (major shifts or creation of common law duties are matter of public policy better left for the legislature).⁷

The only duty imposed on Dr. Sudarshan is the duty to exercise reasonable care in care and treatment. This duty of reasonable care is premised on consensus in the medical community and there is no support whatsoever for an imposition of a due diligence duty and would mark a drastic expansion of existing law and one better left to the legislature not the courts. Because the Complaint fails to allege a viable duty or breach of the standard of care or failed to act as a reasonably prudent physician would under the same or similar circumstances, Count III of Plaintiffs' (Master Short Form) Complaint fails to state a claim upon which relief can be granted.

2. Plaintiffs' Complaint fails to sufficiently allege causation.

Causation is an essential element of a negligence claim. See *Winkle v. Zettler Funeral Homes, Inc.*, 182 Ohio App.3d 195, 2009-Ohio-1724, 912 N.E.2d 151, ¶46 ("The essential elements for a negligence claim are duty, breach of duty, and damage or injury that is a proximate result of the breach."). It consists of factual and proximate cause. Factual cause is the "but for" or "sine qua none" in which the negligent act is deemed the factual cause of an outcome if in the absence of the act, the outcome would not have been avoided. *Wesley v. Walraven*, 2013 WL 544053 (Ohio App. 4 Dist. 2013) citing *Anderson v. St. Francis- St. George*

⁷ See generally, *Bissen v. Fujii*, 446 A.2d 429, 431 (Haw. 1970) ("we should recognize that although courts at times arriving at decisions have taken into consideration social needs and policy it is the paramount rule of the legislature as a coordinate branch of court government to meet the needs and demands of changing times and legislate accordingly"); Stephen Presser, *The Development and Application of Common Law*, 8 Tex. Rev. L. & Pol. 291, 296-97 (2004) ("[role of judge] you recognize that your job is to preserve the past, with its core system of values. You defer to the other institutions of republican government when it comes to policy making ..."); *Badillo v. Am. Branch*, 16 P.3d 435, 441 (Nev. 2001) (lack of consensus as to medical monitoring militates toward rejecting judicial expansion of common law); *Coombes v. Florio*, 877 N.E. 567, 583 (Mass. 2007) (Marshall, C.J. dissenting) (advocating rejection of expanding physicians' tort liability given how reasonable minds may differ on issue).

Hosp., Inc., 77 Ohio St. 3d 82, 84-85, 671 N.E. 2d 225 (1996); Restatement (Third) of Torts, §26 cmt. b (2010). Proximate cause is generally established ““where an original act is wrongful or negligent and in a natural and continuous sequence produces a result which would not have taken place without the act.”” *Strother v. Hutchinson*, 67 Ohio St. 2d 282, 287, 423 N.E.2d 467 (1981), quoting *Clinger v. Duncan*, 166 Ohio St. 216, 217, 141 N.E.2d 156 (1957). “[W]here no facts are alleged justifying any reasonable inference that the acts or failure of the defendant constitute the proximate cause of the injury there is nothing for the jury [to decide], and, as a matter of law, judgment must be given for the defendant.”” *Kemerer v. Antwerp Bd. of Edn.*, 105 Ohio App.3d 792, 796, 664 N.E.2d 1380 (3d Dist. 1995).

Indeed, “legal responsibility must be limited to those causes which are so closely connected to the result and of such significance that the law is justified in imposing liability.” *Wesley, supra citing Johnson v. Univ. Hosp. of Cleveland*, 44 Ohio St. 3d 49, 57, 540 N.E. 2d 1370 (1989). “A court concludes, as a matter of law, whether consequences that are part of a natural and continuous sequence are, because of public policy grounds, too remote to impose liability for negligent acts or omissions.” *Queen City Terminal Inc. v. General Am. Transp. Corp.*, 1993 WL 538922 (Ohio App. 1 Dist. 1993); see also *Powell*, 885 N.E. 2d at 961-64.

It is alleged that that Dr. Sudarshan and CPM were negligent in failing to provide patient-specific prescriptions and/or in providing “fake” patient lists in order to purchase medication from NECC. Assuming arguendo such allegations are true – which they are not – such allegations are insufficient to plead causation, either factual or proximate. NECC’s failure to properly manufacture and apply proper sterility practices as to the preservative-free MPA is the source of the contamination, not Dr. Sudarshan’s alleged failure to provide patient-specific prescriptions. As such, the contamination would have occurred irrespective of whether patient-specific prescriptions were provided when purchasing the medication from NECC. Accordingly,

the allegation that Dr. Sudarshan and/or CPM failed to provide patient-specific prescriptions is insufficient to establish causation as a matter of law.

3. Plaintiffs' Complaint fails to sufficiently allege gross negligence.

Ohio law defines gross negligence as the “failure to exercise any or very slight care” or “a failure to exercise even that care which a careless person would use.” *Posen v. Sitecon, L.L.C.*, 8th Dist. No. 86239, 2006-Ohio-3167, quoting *Thompson Elect., Inc. v. Bank One, Akron, N.A.*, 37 Ohio St.3d 259, 265, 525 N.E.2d 761 (1988). In the absence of any duty, a plaintiff's gross-negligence claim must fail as a matter of law. *Winkle*, 182 Ohio App.3d at 210, citing *Elite Designer Homes, Inc. v. Landmark Partners*, 9th Dist. No. 22975, 2006-Ohio-4079, ¶ 57.

While the allegations in Plaintiffs' Complaint are extensive, they have not alleged sufficient facts against Dr. Sudarshan and CPM to support a gross negligence claim. They are not sufficient to establish Dr. Sudarshan and CPM “fail[ed] to exercise any or very slight care” or “fail[ed] to exercise even that care which a careless person would use” as required to support a gross negligence claim.

B. Under Ohio law, physicians cannot be held liable for violations of the Consumer Sales Practices Act.

In Count IV of their Complaint, Plaintiffs attempt to assert a claim against Dr.. Sudarshan and CPM for purported violations of the Ohio Consumer Sales Practices Act (hereinafter “OCSPA”), O.R.C. § 1345.01 *et seq.* See Short Form Complaint. However, under Ohio law, transactions between physicians and their patients do not fall within the bounds of the OCSPA requiring dismissal of Count IV of Plaintiffs' Complaint.

The OCSPA prohibits a supplier from committing an unfair or deceptive act or practice in connection with a consumer transaction. See R.C. 1345.02(A); see also *U.S. Bank v. Amir*, 8th Dist. NO. 97438, 2012-Ohio-2772, ¶42. A “[c]onsumer transaction” does not include ...

transactions between attorneys, **physicians**, or dentists **and their clients or patients....**” (Emphasis added.) R.C. 1345.01(A). Because the OCSPA requires the unfair or deceptive act to occur in the context of a “consumer transaction”, a patient cannot maintain an action against a physician under the OCSPA. See *Chiropractic Clinic of Solon v. Kutsko*, 92 Ohio App.3d 608, 611, 636 N.E.2d 422 (8th Dist. 1994) (holding a chiropractor fell within the definition of ‘physician’ under R.C. 1345.01(A); therefore, the trial court did not err in dismissing a patient’s claim for alleged violations of the OCSPA); *Summa Health Sys. v. Viningre*, 140 Ohio App.3d 780, 795, 749 N.E.2d 344 (9th Dist. 2000) (recognizing the OCSPA does not apply to claims by patients against physicians).

It is undisputed that Dr. Sudarshan is a physician within the meaning of the OCSPA and any and all claims Plaintiffs may against him, and CPM as his employer, arise in the context of the physician-patient relationship between Plaintiff Joseph Brady and Dr. Sudarshan. Plaintiffs cannot maintain an action against Dr. Sudarshan and CPM for violations of the OCSPA under any circumstance. Therefore, Count IV of fails to state a claim upon which relief can be granted and must be dismissed.

C. Plaintiff Consented to the Steroidal Injections at Issue; Therefore, There Is No Viable Claim for Battery.

Under Ohio law, a person commits battery when he unlawfully strikes or touches another. *Anderson v. St. Francis-St. George Hosp.*, 83 Ohio App.3d 221, 225, 614 N.E.2d 841 (1st Dist. 1992), citing *Green v. Drungold*, 101 N.E.2d 906, 908 (1950). In a medical setting, if a physician treats a patient without authorization or **consent**, the physician has committed a technical battery. (Emphasis added.) *Marcum v. Holzer Clinic, Inc.*, 4th Dist. No. 03CA25, 2004-Ohio-4124, ¶37; *Anderson*, 83 Ohio App.3d 221; *Estate of Leach v. Shapiro*, 13 Ohio App.3d 393, 469 N.E.2d 1047 (9th Dist. 1984).

A physician's acts are lawful if the patient has **expressly consented** to the medical treatment. *Anderson*, 83 Ohio App.3d 221. When a defendant offers proof that a plaintiff has consented to a medical treatment and the plaintiff fails to present evidence that the physician's treatment was performed without consent or that the treatment exceeded his or her consent, there is a failure of proof on an essential element of battery. See *Lipp v. Kwyer*, 6th Dist. No. L-02-1150, 2003-Ohio-3988 (trial court properly granted summary judgment on plaintiff's battery claim where plaintiff consented to procedure employed).

The procedure at issue here is the performance of a epidural steroidal injection. If the plaintiff consented to the performance of the steroidal injection procedures, he is unable to establish the elements of a battery claim. In an attempt to establish his claim for battery, Plaintiff alleges he "did not consent to the injection of contaminated drugs into [his] bod[y]". See Master Complaint at ¶297. However, several paragraphs later, Plaintiff alleges "[m]any, if not all, of the Clinic Related Defendants prepared Consent for Treatment Forms... **which Plaintiffs read and relied upon when agreeing to accept treatment...**" *Id.* at ¶302. Thus, even when accepting all of Plaintiff's allegations as true, he was provided with a Consent to Treatment Form, which he read, prior to agreeing to undergo the steroidal injections at issue and agreeing to accept treatment, i.e. plaintiff consented to the performance of the injections. Accordingly, Count VIII of Plaintiffs' Complaint fails to state a claim upon which relief can be granted and must be dismissed.

D. Plaintiffs' Complaint Does Not Properly Allege Violations of the Ohio Products Liability Act.

1. The Master Complaint does not set forth a claim for violations of Ohio Products Liability law.

Plaintiffs purport to incorporate by reference from the Master Complaint, a claim against Dr. Sudarshan and CPM for alleged violations of the Ohio Products Liability Act (hereinafter "OPLA"). See Short Form Complaints, at p. 4. However, the Master Complaint does not set forth

a claim for violations of the OPLA. To the contrary, Count IX of the Master Complaint sets forth a claim against the Tennessee Clinic Related Defendants only for alleged violations of Tennessee Products Liability law. See Master Complaint at p. 76. Unlike several other counts in the Master Complaint where Plaintiffs set forth statutory claims against the Clinic Related Defendants by listing the various state statutes that formed the basis of such claims – for example, Count IV and Count XII – Count IX is limited to the Tennessee Clinic Related Defendants and sets forth allegations specific to Tennessee law.

Further, in their Short Form Complaint, Plaintiff has not set forth any allegations specific to the Ohio Products Liability claim. Without the necessary allegations in either the Master Complaint or the Short Form Complaint, Plaintiffs have not sufficiently plead a claim for violations of the OPLA in this case.

2. As providers of professional services, Dr. Sudarshan and CPM cannot be held liable for alleged violations of Ohio Products Liability law.

Assuming arguendo Count IX of the Master Complaint is somehow sufficient to set forth a cause of action under the OPLA, the Complaint fails to state a claim as Dr. Sudarshan and CPM cannot be held liable for Plaintiff's alleged injuries under the OPLA.

The OPLA imposes liability on manufacturers and suppliers for damages resulting from defective products. See O.R.C. § 2307.71 et seq. A “manufacturer” can be held liable when the product at issue was defective 1) in manufacture or construction, 2) in design, 3) due to inadequate warning or instruction, or 4) because it did not conform to a representation made by the manufacturer. See O.R.C. § 2307.73. Similarly, a “supplier” can be held liable when the supplier itself was negligent or when the product in question left the supplier, it did not conform to a representation made by the supplier. See O.R.C. § 2307.78(A). In addition, a supplier can be held indirectly liable under several circumstances set forth in O.R.C. § 2307.78(B), including

when, as in this case, the claimant will be unable to enforce a judgment against the manufacturer of that product due to the insolvency of the manufacturer. See O.R.C. § 2307.78(B)(2).⁸

Neither Dr. Sudarshan or CPM constitute a “supplier” under the OPLA. The OPLA defines a “supplier” as: 1) a person that, in the course of a business conducted for the purpose, sells, distributes, leases, prepares, blends, packages, labels, or otherwise participates in the placing of a product in the stream of commerce; or 2) a person that, in the course of a business conducted for the purpose, installs, repairs, or maintains any aspect of a product that allegedly causes harm. O.R.C. § 2307.71(A)(15)(a). The OPLA specifically excludes from the definition of “supplier” a “provider of professional services who, incidental to a professional transaction the essence of which is the furnishing of judgment, skill, or services, sells or uses a product.” O.R.C. § 2307.71(A)(15)(b).⁹

Here, Dr. Sudarshan and CPM do not constitute a “supplier” within the meaning of the OPLA as the preservative-free MPA at issue (the product) was used by Dr. Sudarshan while providing professional services – in the form of medical care and treatment. The use of the preservative-free MPA was merely incidental to the medical services provided by Dr. Sudarshan. Dr. Sudarshan and CPM cannot be held liable as a supplier under the OPLA. Count IX fails to state a claim upon which relief can be granted.

E. Plaintiffs Complaint Does Not Sufficiently Set Forth a Failure to Warn Claim under Ohio Law.

1. The Ohio Products Liability Act abrogates common law failure to warn claims based on an allegedly defective product.

⁸ Under the OPLA, a manufacturer is a “person engaged in a business to design, formulate, produce, create, make, construct, assemble, or rebuild a product or a component of a product.” O.R.C. § 2307.71(A)(9). Here, Dr. Sudarshan and/or CPM do not meet the definition of a manufacture under the OPLA, nor has Plaintiffs set forth any allegations establishing that they do.

⁹ *see also* Restatement (Third) of Torts, Product Liability section 20 cmt. d (1998) (“in a strong majority of jurisdictions, hospitals are held not to be sellers of products they supply in conjunction with the provision of medical care, regardless of circumstances”); 65 ALR 5th 357 (“generally attempts to apply product liability principles to what would be conventional medical malpractice actions have been unsuccessful”).

Ohio Revised Code § 2703.71 defines a “[p]roduct liability claim” as a “claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from ... any warning or instruction, or lack of warning or instruction, associated with that product...” See O.R.C. § 2307.71(A)(13). The OPLA abrogated all common law product liability claims or causes of action. See O.R.C. § 270.371(B); see also *Wimbush v. Wyeth*, 619 F.3d 632, 639 (6th Cir. 2010) (recognizing the OPLA abrogated all common law product liability claims or causes of action).

The essence of the failure to warn claim (Count VIII) is that Dr. Sudarshan and/or CPM failed to warn that plaintiff was being provided or administered an “unsafe, unreasonably dangerous drug compounded by NECC”. Such a claim falls squarely within the definition of a “products liability claim” as it involves the “lack of warning... associated with a product” and, therefore, is abrogated by the OPLA. Dr. Sudarshan and CPM cannot be held liable under the OPLA; therefore, Count VIII fails to state a claim upon which relief can be granted.

2. Plaintiffs’ Complaint fails to establish the necessary elements of a common law failure to warn claim.

Assuming arguendo Plaintiffs failure to warn claim is not abrogated by the OPLA, the Complaint fails to establish the necessary elements of a common law failure to warn claim. To that end, to prove a claim of negligent failure to warn, a plaintiff must establish: (1) **the defendant had a duty to warn**; (2) the duty was breached; and (3) the plaintiff’s injury proximately resulted from the breach of duty. (Emphasis added.) *In re Whirlpool Corp. Front-Loading Washer Products Liab. Litig.*, 722 F. 3d 838, 853 (6th Cir. 2013). A plaintiff must show “that in the exercise of ordinary care, the [defendant] knew or should have known of the risk or hazard about which it failed to warn” and “that the [defendant] failed to take the

precautions that a reasonable person would have taken in presenting the product to the public.”
Id.

The Complaint does not contain any allegations that the use of preservative-free MPA or a compounded drug, generally, presents a high-risk to patients or is unreasonably dangerous. Additionally, the Complaint does not contain any allegations that Dr. Sudarshan and/or CPM knew or should have known that using preservative-free MPA or a compounded drug is unsafe or more dangerous than using a drug produced by an FDA-regulated manufacturer. Further, the Complaint does not allege Plaintiff would have in fact refused to undergo the epidural steroidal injections at issue if he had been informed the drug being used was preservative-free MPA that had been obtained from a compounding pharmacy. Quite simply, the Complaint does not contain the necessary allegations to establish a common law failure to warn claim.

Moreover, Ohio law does not impose a duty on physicians to inform patients where drugs are produced or that a drug being used in the course and scope of their treatment was produced at a compounding pharmacy instead of an FDA-regulated pharmaceutical manufacturer. Thus, any failure on the part of Dr. Sudarshan and/or CPM to provide such information cannot form the basis of a common law failure to warn claim. Count VII is insufficient as a matter of law and must be dismissed.

F. Plaintiffs Complaint Does Not Adequately Allege the Elements Necessary to Create an Agency Relationship under Ohio law.

Ohio law defines an agency relationship as a consensual, fiduciary relationship between two persons where the agent has the power to bind the principal by his or her actions, and the principal has the right to control the actions of the agent. *Evans v. The Ohio State Univ.*, 112 Ohio App.3d 724, 744 (10th Dist. 1996). To that end, an agency relationship exists “when one party **exercises the right of control over the actions of another**, and those actions are directed toward the attainment of an objective which the former seeks.” (Emphasis added.) *Mermer v.*

Medical Correspondence Services, 115 Ohio App.3d 717, 721 (6th Dist. 1996). “The important element in determining the existence of an agency relationship is the existence of control over the conduct and activities of the alleged agent.” *Adlaka v. Valley Elec. Consol., Inc.*, 11th Dist. No. 2007-T-0071, 2008-Ohio-1690, ¶¶27-28. Of note, the party alleging the existence of an agency relationship bears the burden of proving that such a relationship exists. *Nee v. State Indus., Inc.*, 8th Dist. No. 99505, 2013-Ohio-4794, ¶63.

Significantly, the Complaint does not contain any allegations establishing Dr. Sudarshan or CPM exercised the control over the actions of NECC that is necessary to establish an agency relationship between Dr. Sudarshan and/or CPM and NECC. To that end, CPM, and Dr. Sudarshan/CPM and NECC are separate and distinct business entities with no legal relationship linking them together. Plaintiffs have not alleged, nor could he, that Dr. Sudarshan and/or CPM exhibited any control, let alone the amount of control necessary to create an agency relationship, over the actions of NECC.

In an apparent attempt to establish the element of control necessary to create an agency relationship, the Complaint states, in pertinent part: “[Dr. Sudarshan and CPM] controlled the procurement of drugs from NECC...” However, the above-mentioned allegation does not allege the amount or type of control necessary to create an agency relationship. While creative, alleging Dr. Sudarshan and CPM controlled the procurement of drugs from NECC is not remotely tantamount to alleging Dr. Sudarshan and/or CPM controlled the actions of NECC. To the contrary, “controlled the procurement” simply means Dr. Sudarshan and/or CPM purchased medications from NECC. Thus, the only allegation relative to any amount of control between Dr. Sudarshan and/or CPM and NECC is insufficient to establish the control necessary to create an agency relationship under Ohio law.

Simply put, the purchase of medication by a doctor's office from a pharmacy does not create an agency relationship. If such acts created an agency relationship, nearly every retailer would be acting as an agent of every consumer that has ever made any purchase with the retailer. Because the purchase of medication from a pharmacy is an act of free choice and does not require or exhibit a scintilla of control by the doctor's office over the pharmacy, Plaintiffs cannot establish the level of control necessary to hold Dr. Sudarshan and CPM liable for the actions of NECC. Accordingly, the allegations in the Complaint do not set forth the necessary elements of an agency relationship sufficient to hold Dr. Sudarshan and CPM liable for the actions of NECC. Count X of the Complaint must be dismissed.

G. The Allegations in Plaintiffs' Complaint Do Not Meet the Requirements of a Civil Conspiracy Claim under Ohio Law.

Ohio defines civil conspiracy as “a malicious combination of two or more persons to injure another in person or property, in a way not competent for one alone, resulting in actual damages.” *Fed. Ins. Co. v. Webne*, 513 F. Supp.2d 921, 926-27 (N.D. Ohio 2007). To establish a claim of civil conspiracy, a plaintiff must allege: 1) a malicious combination; 2) of two or more persons; 3) injury to person or property; and 4) **existence of an unlawful act independent from the actual conspiracy**. (Emphasis added.) *Id.* Malice “is that state of mind under which a person does a wrongful act purposely, without a reasonable or lawful excuse, to the injury of another.” *Ohio Bureau of Workers' Comp. v. MDL Active Duration Fund, Ltd.*, 476 F. Supp.2d 809, 825 (S.D. Ohio 2007). An underlying unlawful act or tort is required before a party can prevail on a civil conspiracy claim. *Dickerson Internationale, Inc. v. Klockner*, 139 Ohio App.3d 371, 380, 743 N.E.2d 984 (2nd Dist. 2000).

The allegations set forth in the Complaint do not meet the requirements of a civil conspiracy claim. The Complaint does not allege a “malicious combination” between Dr. Sudarshan and/or CPM and NECC. While it is alleged that defendants’ “acted in concert”, such

an allegation is not a properly pled factual allegation necessary to survive a motion to dismiss. Also it does not rise to the level of a “malicious combination” as there is no allegation Dr. Sudarshan and/or CPM acted with the purpose or intent of circumventing the Massachusetts Board of Pharmacy rules and regulations or that Dr. Sudarshan and CPM purposely or intentionally provided “fake” patient lists – which they did not. Additionally, the Complaint does not set forth any allegations that Dr. Sudarshan and/or CPM acted with the purpose or intent to injure.

Finally, the Complaint fails to allege an unlawful act on the part of Dr. Sudarshan and CPM separate and apart from the alleged conspiracy. As Dr. Sudarshan and CPM are not in Massachusetts, did not provide treatment to Plaintiffs in Massachusetts, are not pharmacists and/or licensed by the Massachusetts Board of Pharmacy, nor are they subject to the rules and regulations of the Massachusetts Board of Pharmacy. Accordingly, their alleged violation of such rules and regulations does not constitute an “unlawful act”. Further, failing to provide patient lists and/or providing a “fake” list of patient names to NECC pursuant to its own request is not an “unlawful act independent from the actual conspiracy” for which Dr. Sudarshan and CPM can be held liable.

The Complaint fails to adequately factually allege a claim for civil conspiracy under Ohio law. They have failed to allege both a malicious combination on the part of Dr. Sudarshan and/or CPM or that either Defendant acted for the purpose of injuring Plaintiffs. Furthermore, neither Dr. Sudarshan nor CPM had any duty to abide by the rules and regulations of the Massachusetts Board of Pharmacy or provide it with patient lists to purchase preservative-free MPA from NECC. Thus, in addition to failing to properly allege the first and second elements of a civil conspiracy claim, Plaintiffs have not alleged an underlying unlawful act by Dr. Sudarshan or CPM. Count XI of the Complaint must be dismissed.

H. The Allegations Against Dr. Sudarshan and CPM are Insufficient to Support a Punitive Damages Claim under Ohio Law.

In Count XIV of the Complaint, Plaintiffs have attempted to assert a punitive damages claim against Dr. Sudarshan and CPM. See Master Complaint at p. 86; Short Form Complaint at 4. However, none of the allegations are sufficient to support a punitive damages claim. Indeed, a punitive damages claim is a derivative claim that cannot stand when the underlying tort claims are insufficient as a matter of law. Accordingly, Count XIV of the Complaint fails to state a claim upon which relief can be granted.

Under Ohio law, courts may award punitive damages in a tort action only upon a finding that the defendant committed a fraud or insult or that the defendant acted with “actual malice.” *Preston v. Murty*, 32 Ohio St.3d 334, 334-335, 512 N.E.2d 1174 (1987). The Ohio Supreme Court has defined “actual malice” as “(1) that state of mind under which a person’s conduct is characterized by hatred, ill will or a spirit of revenge, *or* (2) a conscious disregard for the rights and safety of other persons that has a great probability of causing substantial harm.” (Emphasis sic.) *Id.* at syllabus.

Significantly, malice of the “conscious disregard” variety requires a higher culpability than acting “knowingly” under the Ohio criminal code and a higher culpability than acting with “recklessness” under the Restatement (2d) of Torts. *Spalding v. Coulson*, 8th Dist. Nos. 70524/70538, 1998 WL 564054, *16 (Sept. 3, 1998). In that regard, in *Spalding*, the court stated, in pertinent part:

In short, to warrant the imposition of additional punitive damages, above and beyond compensatory damages, the tort must be committed with a particularly depraved mental state. **In its basest form, it requires showing not only that the tortfeasor intended his act, but also deliberately intended to injure others. Its lesser forms include the tortfeasor’s perverse willingness to ignore consciously almost certain injury from his action.** The imminent harm disregarded must be substantial. **Recklessness, carelessness, or ignorance of the actor do not justify the imposition of punitive damages.** (Citations omitted.)

(Emphasis added.) *Id.* Thus, “a principle inherent in the award of punitive damages is that something more than mere negligence is always required.” *Preston*, 32 Ohio St.3d at 335, citing *Leichtamer v. American Motors Corp.*, 67 Ohio St.2d 456, 472, 424 N.E.2d 568 (1981). Further, otherwise sufficient evidence of compensatory damages will not automatically result in an assessment of punitive damages. *Motorists Mut. Ins. Co. v. Said*, 63 Ohio St.3d 690, 696, 509 N.E.2d 1228 (1992).

When proceeding on the “conscious disregard” definition of malice under *Preston*, a punitive damages claim requires proof of the defendant’s subjective knowledge of the danger posed to another by his conduct. *Estate of Schmidt v. Derenia*, 158 Ohio App.3d 738, 743-744, 822 N.E.2d 401 (10th Dist. 2004). “Since punitive damages are assessed for punishment and not compensation, a positive element of conscious wrongdoing is always required.” *Preston*, 32 Ohio St.3d at 335. The party must possess knowledge of the near certainty that substantial harm will be caused by the tortious behavior. *Estate of Schmidt*, 158 Ohio App.3d at 743-744. “Any less callous mental state is insufficient to incur that level of societal outrage necessary to justify an award of punitive damages.” *Motorists Mut. Ins. Co.*, 63 Ohio St.3d at 698, citing *Preston*, 32 Ohio St.3d at 336.

The Complaint does not contain any allegations sufficient to establish Dr. Sudarshan and CPM acted with the actual malice necessary to support a claim for punitive damages in this case. To that end, Plaintiff has not set forth any allegations establishing that at the time of Plaintiffs respective injections, Dr. Sudarshan intended to inject him with medication that may be contaminated. Accordingly, the Complaint does not adequately set forth a claim for punitive damages under the first prong of *Preston*.

While Plaintiffs have set forth the bare legal conclusion that Dr. Sudarshan “were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that [his]

disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under the circumstances”, they have not set forth sufficient factual allegations to support the assertion that either Dr. Sudarshan was aware, or should have been aware, of any substantial and unjustifiable risk posed by using preservative-free MPA obtained from NECC. Specifically, they have not set forth any allegations sufficient to establish Dr. Sudarshan had the subjective knowledge of the danger posed by purchasing preservative-free MPA from NECC that is required under the second-prong of *Preston*.

Plaintiffs have likewise not cited to any Ohio law, either common law or statutory, that establishes any duty on the part of Dr. Sudarshan to 1) purchase medications from a FDA-approved manufacturer, or 2) ensure NECC was in compliance with Massachusetts pharmaceutical laws, or 3) inspect and/or visit NECC’s facilities prior to purchasing preservative-free MPA from it. Even allegations of, “[r]ecklessness, carelessness, or ignorance of the actor do not justify the imposition of punitive damages” under Ohio law. *Spalding*, 1998 WL 564054 at *16.

Further, the Ohio Supreme Court has held that “no civil cause of action in this state may be maintained simply for punitive damages.” *Intercity Auto Sales, Inc. v. Evans*, 8th Dist. No. 95778, 2011-Ohio-1378, ¶27, quoting *Niskanen v. Giant Eagle, Inc.*, 122 Ohio St.3d 486, 2009–Ohio–3626, 912 N.E.2d 595, ¶ 13; see also *Moskovitz v. Mt. Sinai Med. Ctr.*, 69 Ohio St.3d 638, 650, 1994–Ohio–324, 635 N.E.2d 331, which held that, since “punitive damages are awarded as a mere incident of the cause of action in which they are sought * * *, compensable harm stemming from a cognizable cause of action must be shown to exist before punitive damages can be considered.” Plaintiffs have not set forth a cognizable cause of action against Dr. Sudarshan and CPM. Accordingly, the claim for punitive damages is insufficient under Ohio law., Dr. Sudarshan and CPM are entitled to dismissal of Count XIV of Plaintiff’s Complaint.

V. CONCLUSION

For the foregoing reasons, Defendants, Gururau Sudarshan, M.D., Cincinnati Pain Management Consultants, Inc. and Cincinnati Pain Management Consultants, Ltd., respectfully request the Complaint in *Brady, et al. v. Unifirst Corporation, et al.*, No. 1:14-cv-10284-RWZ be dismissed, with prejudice, pursuant to Fed.R.Civ.P. 12(b)(6).

Respectfully Submitted
The Defendants
Gururau Sudarshan, M.D., Cincinnati Pain
Management Consultants, Inc. and Cincinnati Pain
Management Consultants, Ltd.
By their attorney

/s/ Tory A. Weigand

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on **March 14, 2014**

/s/ Tory A. Weigand

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